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Philippe Chavignac

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EXAMINER

STUART, COLIN W

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,643	Applicant(s) CHALVIGNAC, PHILIPPE	
	Examiner COLIN STUART	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-16 and 18-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-16 and 18-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 May 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to the request for continued examination filed on 5/21/10. As directed by the amendment, claims 1 and 15 have been amended and no claims have been added nor cancelled.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3-4, 6-9, 11, 13, 15-16, 18-20, and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brydon et al. (5,740,795) in view of Kullik et al. (6,895,962).

In regards to claims 1 and 3, Brydon shows a breathing assistance device which includes a turbine 14 to generate a flow of pressurized respiratory gas, a duct ("air delivery tube (not shown)" col. 3 ln. 31) adapted to carry the pressurized gas to a patient, and control means 18 for controlling gas pressure capable of computing a pressure setting for the turbine. Brydon's device also inherently has a speed sensor capable of acquiring a signal corresponding to a rotation speed of a rotating element of the turbine ("motor speed" col. 3 ln. 8). Turbines inherently have a rotating element which is directly related to the speed of the turbine. Brydon's device further includes means of calculation (col. 3 ln. 10-23) connected to the speed sensor to computer the

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pressure setting of the turbine using the signal from the speed sensor ("speed feedback signal 22 is input to the motor controller 18 to provide a signal upon which speed regulation can be based" col. 3 In. 37-39). Brydon's device includes means of calculation which use speed signals "to detect the points at which the patient starts to inhale or exhale" (col. 3 In. 15-16) and adapts the level of pressure setting (col. 3 In. 37-39, but does not teach explicitly teach computing pressure setting based on detecting new inspiratory or expiratory cycles using only the speed signal. However, one of ordinary skill in the art at the time the invention was made would have found it obvious to use only the speed signal and would expect the Brydon's device to perform equally as well. The Brydon device is silent as to the turbine having an inertia less than about 200 g.cm^2 ; however, Kullik teaches a breathing assistance device which includes a turbine having an inertia less than about 200 g.cm^2 (see Kullik col. 3 In. 13-15). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the turbine of Brydon's device to have an inertia less than about 200 g.cm^2 as taught by Kullik in order to make "possible respiration with different respiration pressures" (see Kullik col. 1 In. 20-21).

In regards to claim 4, the modified Brydon device includes calculation means which use the speed signals to compute a pressure setting according to variations in speed (Brydon "these measured signals vary" col. 3 In. 10).

In regards to claims 6, 7, and 11, the modified Brydon device also includes a "microcomputer where the subsequent signal processing described above is performed" (Brydon col. 4 In. 38). This microcomputer employs signal processing programs to

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detect "the start of inhalation and exhalation" (Brydon col. 3 ln. 67 - col. 4 ln. 1). The programs use "previously determined pressure/flow/speed characteristics of the turbine system" (Brydon col. 3 ln. 12-14), which are stored in a memory of the device's control means 18, along with the actual instantaneous speed signal (Brydon 22) and "threshold value for detecting inhalation and exhalation" (Brydon col. 4 ln. 25-26). Brydon's reference discloses an "instantaneous power signal" (col. 3 ln. 60) which is employed in the signal processing and is directly related to the instantaneous speed of the turbine. The speed signal is the speed bearing as in claim 7 because direction of the flow can be ascertained in that a positive value would indicate flow going into the patient.

In regards to claim 8, the modified Brydon device has everything as claimed including speed sensor and a computer (calculation means) which uses previously determined values which are stored in a memory of the device's control means (Brydon 18). Brydon lacks a detailed description of using a program to detect an inspiratory cycle using a comparison between a memorized speed value representative of a speed at the end of an expiratory cycle and an actually measured instantaneous speed. However, the feature of comparing the predetermined speed to the real time speed is well known in the art for obtaining desired speed. In addition, using a program to calculate or determine the desired speed is common practice and is necessary for carrying out the calculations. Furthermore, Brydon's reference is capable of obtaining a speed at the end of expiratory cycles. Thus, the feature of having a program to compare the memorized speed value at the end of the expiratory cycle and the actual measured speed fails to patentably define over the prior art.

In regards to claims 9 and 21, the modified Brydon device employs a microcomputer to perform signal processing and comparison as discussed above but is silent as to using several programs for comparison. However, one of ordinary skill in the art at the time of the invention would have found it obvious to use various programs simultaneously for comparison to increase the accuracy of the inhalation/exhalation detecting process.

In regards to claim 13, the modified Brydon device uses a microcomputer, which is a microprocessor, to perform signal processing and comparison of the speed signals to detect inhalation/exhalation cycles.

In regards to claims 15-16, 18-20, and 23-24, the modified Brydon device lacks a detailed description of the claimed method steps. However, Brydon's system has the same structure as claimed. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made upon seeing Brydon's system, that the system would be able to perform the claimed method steps.

4. Claims 10, 12, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brydon (5,740,795) and Kullik et al. (6,895,962) as applied to claims 6, 11, or 18 above, and further in view of Rapoport et al. (5,803,066).

In regards to claims 10 and 22, the modified Brydon device teaches all the limitations as discussed above, but, as best understood, is silent as to providing that the device is configured to be disabled to compensate for the momentary pause between inspiratory and expiratory cycles. However, Rapoport teaches a breathing assistance

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device and control method which includes a pause state which allows the "machine is in transition from INSP to EXP, or from EXP to INSP" (Rapoport col. 7 ln. 56-57) for a determined duration following the start of the cycle. Therefore, one of ordinary skill in the art at the time the invention was made would have found it obvious to modify the modified Brydon's device and method to include a disabling means, or pause state, as taught by Rapoport in order to provide a more accurate control method for the breathing assistance device.

In regards to claim 12, the modified Brydon device teaches all the limitations as discussed above including previously determined and stored in memory speed values, but is silent as to the memorized turbine speed values being maximum values for an inspiratory cycle. However, Rapoport teaches a breathing assistance device and control method in which the "system determines the maximum inspiratory flow value" (Rapoport col. 8 ln. 39-40). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Brydon's device and method to also use memorized maximum turbine speed values for an inspiratory, as taught by Rapoport, in its comparison method in order to provide a more accurate control method as the modified method would be taking measurements from points through out the respiration cycles as opposed to focusing on the transitions from inspiratory to expiratory cycles.

5. Claims 2 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brydon (5,740,795) and Kullik et al. (6,895,962) as applied to claims 1 or 18 above, and further in view of Farrugia et al. (6,332,463).

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In regards to claim 2, the modified Brydon device teaches all the limitations as discussed above, but is silent as to the speed sensor being a Hall effect sensor.

However one of ordinary skill in the art at the time of the invention would have found this to be a matter of obvious design choice as a Hall effect sensor is well-known in the art and further taught by Farrugia's breathing assistance control method (Abstract line 3).

In regards to claim 14, the modified Brydon device teaches all the limitations as discussed above including a circuit which connects the speed sensor, calculation means, and turbine for computing the speed setting input for the turbine (Brydon col. 4 In. 36-48, but is silent as to the pressure-regulating "feedback loop" (Brydon col. 2 In. 58) further including a pressure sensor on the duct. However, Farrugia teaches a breathing assistance device and control method which includes a pressure sensor (42 Farrugia) which is connected to breathing tube, or duct, (40 Farrugia). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Brydon's reference to include a pressure sensor as taught by Farrugia in order to provide a more direct, and accurate, measurement of the pressure of the breathing gas delivered to a patient.

Response to Arguments

6. Applicant's arguments with respect to claims 1 and 15 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following documents are considered to be pertinent art: Jafari et al. (6,626,175), Champain et al. (5,443,061), and Servidio et al. (5,927,274) are all related to ventilation regulation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to COLIN STUART whose telephone number is (571)270-7490. The examiner can normally be reached on M-F 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COLIN STUART/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771

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